



Docket No. 76581/JPW/LCM

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Jacob Bar-Tana et al.
Serial No. : 10/585,017
Filed : June 28, 2006
For : Methods Of Administering 3,3,14,14 Tetramethyl Hexadecane 1,16 Dioic Acid

1185 Avenue of the Americas
New York, New York 10036
August 13, 2008

Commissioner for Patents
P.O. BOX 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants submit this Information Disclosure Statement. Applicants direct the Examiner's attention to the following items, which are also listed on the Substitute Form PTO-1449 attached hereto as **Exhibit A**. In accordance with 37 C.F.R. §1.98(a)(2)(ii), copies of U.S. Patents and U.S. Patent Application Publications need not be provided. Accordingly, copies of the documents listed as items 1-18 are not submitted herewith. Copies of items 19-37 are attached hereto as **Exhibits 1-19**.

This Information Disclosure Statement is being submitted under 37 C.F.R. §1.97(b)(3) before the mailing of the mailing of the first Office Action on the merits. Thus, this Information Disclosure Statement should be entered and considered.

1. U.S. Patent No. 4,634,795, Bar-Tana, issued January 6, 1987;

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2. U.S. Patent No. 4,689,344, Bar-Tana, issued August 25, 1987;
3. U.S. Patent No. 4,711,896, Bar-Tana, et al., issued December 8, 1987;
4. U.S. Patent No. 5,641,810, Pill, et al., issued June 24, 1997;
5. U.S. Patent No. 6,284,903, Bar-Tana, issued September 4, 2001;
6. U.S. Patent No. 6,303,653, Bar-Tana, issued October 16, 2001;
7. U.S. Patent No. 5,225,182, Sharma, issued July 6, 1993;
8. U.S. Patent No. 5,169,383, Gyory, et al., issued December 8, 1992;
9. U.S. Patent No. 5,167,616, Haak, et al., issued December 1, 1992;
10. U.S. Patent No. 4,959,217, Sanders, et al., issued September 25, 1990;
11. U.S. Patent No. 4,925,678, Ranney, issued May 15, 1990;
12. U.S. Patent No. 4,487,603, Harris, issued December 11, 1984;
13. U.S. Patent No. 4,486,194, Ferrara, issued December 4, 1984;
14. U.S. Patent No. 4,447,233, Mayfield, issued May 8, 1984;
15. U.S. Patent No. 4,447,224, DeCant, Jr., et al., issued May 8, 1984;

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16. U.S. Patent No. 4,439,196, Higuchi, issued March 27, 1984;
17. U.S. Patent No. 4,475,196, La Zor, issued October 2, 1984;
18. U.S. Patent No. 6,303,653, Bar-Tana, issued October 16, 2001;
19. WO98/030530, Bar-Tana, issued July 16, 1998 (**Exhibit 1**);
20. WO99/00116, Bar-Tana, issued January 7, 1999 (**Exhibit 2**);
21. Atkinson, L.L., et al., (2002) "MEDICA 16 inhibits hepatic acetyl-CoA carboxylase and reduces plasma triacylglycerol levels in insulin-resistant JCR: LA-cp rats" *Diabetes*, 51(5):1548-1555 (**Exhibit 3**);
22. Bar-Tana, J., et al., (1989) "Synthesis and hypolipidemic and antidiabetogenic activities of beta,beta,beta',beta'-tetrasubstituted, long-chain dioic acids" *Journal of Medicinal Chemistry*, 32(9):2072-2084 (**Exhibit 4**);
23. Bar-Tana, J., et al., (1988) "Hypolipidemic effect of beta, beta'-methyl-substituted hexadecanedioic acid (MEDICA 16) in normal and nephrotic rats" *Journal of Lipid Research*, 29(4):431-441 (**Exhibit 5**);
24. Bar-Tana, J., et al., (1985) "Inhibition of lipid synthesis by beta beta'-tetramethyl-substituted, C14-C22, alpha, omega-dicarboxylic acids in the rat in vivo" *The Journal of Biological Chemistry*, 260(14):8404-8410 (**Exhibit 6**);
25. Frenkel, B., et al., (1994) "The effect of beta,beta'-tetramethylhexadecanedioic acid (MEDICA 16) on plasma very-low-density lipoprotein metabolism in rats: role of apolipoprotein C-III" *The Biochemical Journal*, 298(Pt

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2):409-414 (**Exhibit 7**);

26. Frenkel, B., et al., (1988) "The hypochylomicronemic effect of beta,beta'-methyl-substituted hexadecanedioic acid (MEDICA 16) is mediated by a decrease in apolipoprotein C-III" *The Journal of Biological Chemistry*, 263(17):8491-8497 (**Exhibit 8**);
27. Guerrero-Romero, F., et al., (2001) "Glucose intolerance is predicted by the high Fasting Insulin-to-Glucose ratio" *Diabetes & Metabolism*, 27(2 Pt 1):117-121 (**Exhibit 9**);
28. Kalderon, B., et al., (2003) "Adipose tissue sensitization to insulin induced by troglitazone and MEDICA 16 in obese Zucker rats in vivo" *American Journal of Physiology, Endocrinology and Metabolism*, 284(4):E795-803 (**Exhibit 10**);
29. Kalderon, B., et al., (1992) "Effect of thyroid hormone treatment on redox and phosphate potentials in rat liver" *Endocrinology*, 131(1):400-407 (**Exhibit 11**);
30. Katz, A., et al., (2000) "Quantitative insulin sensitivity check index: a simple, accurate method for assessing insulin sensitivity in humans" *The Journal of Clinical Endocrinology and Metabolism*, 85(7):2402-2410 (**Exhibit 12**);
31. Matthews, D.R., et al., (1985) "Homeostasis model assessment: insulin resistance and beta-cell function from fasting plasma glucose and insulin concentrations in man" *Diabetologia*, 28(7):412-419 (**Exhibit 13**);
32. Mayorek, N., et al., (1997) "Sensitization to insulin induced by beta,beta'-methyl-substituted hexadecanedioic acid (MEDICA 16) in obese Zucker rats in vivo" *Diabetes*, 46(12):1958-1964 (**Exhibit 14**);

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33. Mayorek, N., et al., (1993) "Hypocholesterolaemic effect of beta beta'-methyl-substituted hexadecanedioic acid (MEDICA 16) in the male hamster" *The Biochemical Journal*, 289 (Pt 3):911-917 (**Exhibit 15**) ;
34. Rose-Kahn, G., et al., (1985) "Inhibition of lipid synthesis by beta beta'-tetramethyl-substituted, C14-C22, alpha, omega-dicarboxylic acids in cultured rat hepatocytes" *J Biol Chem*, 260(14):8411-8415 (**Exhibit 16**) ;
35. Russell, J.C., et al., (1991) "Hypolipidemic effect of beta, beta'-tetramethyl hexadecanedioic acid (MEDICA 16) in hyperlipidemic JCR:LA-corpulent rats" *Arteriosclerosis and Thrombosis : A Journal of Vascular Biology / American Heart Association*, 11(3):602-609 (**Exhibit 17**) ;
36. Tzur, R., et al., (1989) "Adipose reduction by beta,beta'-tetramethyl-substituted hexadecanedioic acid (MEDICA 16)" *International Journal of Obesity*, 13(3):313-326 (**Exhibit 18**) ;
37. Tzur, R., et al., (1988) "Hypolipidemic, antiobesity, and hypoglycemic-hypoinsulinemic effects of beta,beta'-methyl-substituted hexadecanedioic acid in sand rats" *Diabetes*, 37(12):1618-1624 (**Exhibit 19**) ;

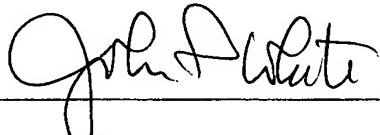
Applicants request that the Examiner review the publications and make them of record in the subject application.

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If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

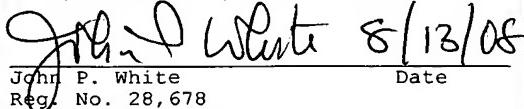
No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

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John P. White Date
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